K082317

SEP 26 2008

Attachment A
510 (k) Summary of Safety and Effectiveness
Prepared in accordance with 21 CFR Part 807.92(c).

GE Healthcare

Section a):

1. Submitter: GE Medical Systems Ultrasound and Primary Care Diagnostics, LLC, a division of the General Electric Company
GE Medical Systems Lunar (business name)
726 Heartland Trail
Madison, WI 53717

Contact Person: James P. Raskob
Safety and Regulatory Engineering Manager
Telephone: 608-826-7425; Fax: 608-299-2132

Date Prepared: August 12, 2008

2. Device Name: GE Lunar FRAX™ 10-year fracture risk software option
Bone Densitometer, 21 CFR 892.1170, 90-KGI

3. Marketed Device: Fracture Risk for DPX bone densitometers K983271
Fracture Risk from BMD using Hologic QDR x-ray Bone Densitometers K983028

4. Device Description: The FRAX™ 10-Year Fracture Risk software option for GE Lunar Bone densitometers provides a 10- year fracture risk assessment based on patient's bone mineral density T-score and clinical risk factors using the FRAX™ WHO Fracture Risk Assessment Tool.

5. Indications for Use: FRAX™ 10-Year Fracture Risk Software Option for GE Lunar Bone Densitometers

The FRAX™ 10-Year Fracture Risk software option is an accessory to currently marketed GE Lunar bone densitometer devices, which are intended to estimate the bone mineral density and body composition (lean and fat tissue mass) of patients when medically indicated by their physicians.

This software option is intended to provide an assessment of 10-year fracture risk. The option provides an estimate of 10-year probability of hip fracture and 10-year probability of a major osteoporotic fracture (clinical spine, forearm, hip or shoulder fracture). This estimate is based on the patient's age, sex, country, ethnicity, height, weight, femur neck BMD T-score, and the presence or absence of several risk factors and is computed using the FRAX™ Fracture Risk Assessment Tool endorsed by the World Health Organization (WHO). The tool has been validated for men and post-menopausal women between 40 and 90 years old. The output is provided in a separate screen display and report that can be viewed or printed or exported to an optional physician report generator tool.

The results can be used by a physician in conjunction with other clinical risk factors as an aid in the diagnosis of osteoporosis and medical conditions leading to reduced bone density, and ultimately in the assessment of fracture risk.

6. Comparison with Predicate Device: The GE Lunar FRAX™ 10-year Fracture Risk Software Option for GE Lunar DXA Bone Densitometers is of a comparable type and substantially equivalent to the Fracture Risk for DPX bone densitometers and Fracture Risk from BMD using Hologic QDR x-ray Bone Densitometers. It has the same technological characteristics, is comparable in key safety and effectiveness features, it utilizes similar design, construction, and materials, and has similar intended uses as the predicate devices.

Section b):

1. Non-clinical Tests: The device has been evaluated for conformance to its design specifications and applicable industry standards for software development. Design verification tests of the software option were performed using a series of test cases from published data. These tests confirmed outputs from the GE Lunar FRAX™ 10-year Fracture Risk Software were consistent with the independent outputs published that utilized the WHO 10-year fracture probability algorithm for specific age, sex, country, ethnicity, height, weight, femur neck BMD T-score, and the presence or absence of several clinical risk factors.

2. Clinical Tests: No new clinical studies were required to establish safety or effectiveness of the new software option. Published literature describing the development and clinical validation of the FRAX™ WHO Fracture Risk Assessment Tool were provided.

   The FRAX™ model is based on a large collection of data. Appropriate clinical risk factors for fracture were determined from eleven large cohort studies. The FRAX™ model was then developed from baseline and follow up data from nine prospective, population-based cohorts, including centers in North America, Europe, Asia, and Australia, consisting of 46,340 people and 189,852 person years of follow-up, during which 850 hip fractures and 3318 other osteoporotic fractures were reported. Data were generally randomly selected and analyzed according to accepted epidemiological practices. All data were published in peer-reviewed journals.

   The performance characteristics determined from the primary cohorts were then validated in eleven independent, population-based cohorts that did not participate in the model synthesis. The validation cohorts consisted of 230,486 subjects representing 1,208,528 patient years of follow-up, during which 3360 hip fractures and 15,183 other osteoporotic fractures occurred.

3. Conclusion: Intended uses and other key features are consistent with previously cleared bone densitometer fracture risk software options. The design and development process of the manufacturer conforms with 21 CFR 820 and ISO 13485 quality systems. The device conforms to applicable medical device safety standards and compliance was verified through ongoing internal and independent quality system audits. Therefore, the GE Lunar FRAX™ 10-year Fracture Risk Software Option for GE Lunar DXA Bone Densitometers is substantially equivalent to currently marketed devices with respect to intended use and safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 2 6 2008

Mr. James P. Raskob
Safety and Regulatory Engineering Manager
General Electric Co.
GE Medical Systems Lunar
726 Heartland Trail
MADISON WI 53717

Re: K082317
Trade/Device Name: FRAX™ 10-Year Fracture Risk Software Option for GE Lunar Bone Densitometers
Regulation Number: 21 CFR 892.1170
Regulation Name: Bone Densitometer
Regulatory Class: II
Product Code: KGI
Dated: August 12, 2008
Received: August 13, 2008

Dear Mr. Raskob:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Joyce M. Whang, Ph.D.
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Attachment D

510 (k) Indications for Use

510(k) Number (if known): K082317

Device Name: **FRAX™ 10-Year Fracture Risk Software Option for GE Lunar Bone Densitometers**

The FRAX™ 10-Year Fracture Risk software option is an accessory to currently marketed GE Lunar bone densitometer devices, which are intended to estimate the bone mineral density and body composition (lean and fat tissue mass) of patients when medically indicated by their physicians.

This software option is intended to provide an assessment of 10-year fracture risk. The option provides an estimate of 10-year probability of hip fracture and 10-year probability of a major osteoporotic fracture (clinical spine, forearm, hip or shoulder fracture). This estimate is based on the patient's age, sex, country, ethnicity, height, weight, femur neck BMD T-score, and the presence or absence of several risk factors and is computed using the FRAX™ Fracture Risk Assessment Tool endorsed by the World Health Organization (WHO). The tool has been validated for men and post-menopausal women between 40 and 90 years old. The output is provided in a separate screen display and report that can be viewed or printed or exported to an optional physician report generator tool.

The results can be used by a physician in conjunction with other clinical risk factors as an aid in the diagnosis of osteoporosis and medical conditions leading to reduced bone density, and ultimately in the assessment of fracture risk.

Prescription Use XXX (Part 21 CFR 801 Subpart D) ~~AND/OR~~ ~~Over-The-Counter Use~~ _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K082317